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Group Art Unit: 1638

REMARKS/ARGUMENTS

Claims 78, 79, 90, 91, 96, 103, 105, 108, and 112-120 are pending in the application.

Claims 78, 96, 108, and 117-120 are cancelled without prejudice or disclaimer. Applicants reserve the right to pursue cancelled claims in a divisional or continuation application.

Claims 79, 103, 105, and 112-116 have been amended. Support for the amendments resides throughout the specification and in the claims as originally filed. No new matter has been added by way of the amendments.

Claims 112-116 have been amended to recite: "...barley alpha-hordothionin...". Support for the amendment is found in the specification on page 8, lines 18-22.

Claims 112-116 have been amended to recite: "...one or more of...". Support for the amendment is found in the specification on page 6, lines 18-21.

Reexamination and reconsideration of the claims is respectfully requested.

Rejections under 35 U.S.C. §112

Claims 78, 79, 90, 91, 96, 103, 105, 108, and 112-120 are rejected under 35 USC §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Office Action states: "Claims 112-120 and all claims dependent thereon, are indefinite in the recitation of 'native plant seed protein' since it is unclear what the metes and bounds of this term would be."

Claims 78, 96, 108, and 117-120 have been cancelled without prejudice. Claims 112-116 have been amended to delete the recitation of "native plant seed protein". It is believed the amendment obviates the rejection.

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The Office Action states: "Claims 113-120 and all claims dependent thereon, are indefinite in that they are unduly alternative in the multiple recitations of 'and/or' in the claims.

Claims 117-120 have been cancelled without prejudice. Claims 113-116 have been amended to replace "and/or" with "one or more of". It is believed the amendment obviates the rejection.

Claims 114-116 are rejected under 35 USC §112, first paragraph as failing to comply with the written description requirement.

The Office Action states: "The claims have been amended to recite 'chimeric'. However, it appears that there is no support for this term in the specification."

Claims 114-116 have been amended to delete the recitation of "chimeric". It is believed the amendment obviates the rejection.

Claims 78, 79, 90, 91, 96, 103, 105, 108 and 112-120 are rejected under 35 USC §112 first paragraph as failing to comply with the enablement requirement.

The Office Action states: "The specification does not teach the range of 7 mole % to 40 mole % of lysine or 6 mole % to 40 mole % of sulfur-containing amino acids for any seed protein and further does not teach any seed proteins having both of these ranges. Therefore, in view of the reasons of record set forth ... it would require undue experimentation by one of ordinary skill in the art to make and/or use the claimed invention."

Claims 78, 96, 108, and 117-120 have been cancelled without prejudice. Claims 112-116 have been amended to replace "...native plant seed protein..." with "...*barley alpha-hordothionin* protein modified to contain *one or more* of about 7 mole % to 40 mole % of lysine or 6 mole % to 40 mole % of a sulfur-containing amino acid...".

It is believed the specification provides the necessary disclosure for one of skill in the art to make and use the invention commensurate in scope with the present claims. Table 1, page 40 of the specification demonstrates increased lysine and cysteine obtained by using constructs comprising the modified barley alpha-

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hordothionin (HT12) and seed-preferred promoters. The 1.132 Declaration signed by co-inventor Rudolf Jung and submitted October 18, 1999 provides results that demonstrate the effectiveness of using a construct comprising HT12 and an endosperm-preferred promoter to increase lysine, cysteine and methionine.

Rejections under 35 U.S.C. §102

Claims 78, 79, 90, 91, 96, 103, 105, 108, and 112-120 are rejected under 35 USC §102(e) as being anticipated by Falco et al (US Patent 5,773,691).

The Office Action states: "The Examiner maintains that Falco does teach an endosperm specific promoter operably linked to DNA encoding lysine rich proteins that meet all the limitations of the present claims"

Claims 78, 96, 108, and 117-120 have been cancelled without prejudice. Claims 112-116 have been amended to replace "...native plant seed protein..." with "...*barley alpha-hordothionin* protein modified to contain *one or more* of about 7 mole % to 40 mole % of lysine or 6 mole % to 40 mole % of a sulfur-containing amino acid...".

Falco et al does not teach the modified barley alpha-hordothionin protein (HT12) as claimed in the present claims and thus cannot be an anticipatory reference under 35 USC §102.

Rejections under 35 U.S.C. §103

Claims 78, 79, 90, 96, 103, 105, 108, and 112-120 remain rejected under 35 USC 103(a) as being obvious over Rao et al (US Patent 5,885,802) in view of the applicant's admission.

The rejection is maintained for the reasons of record as set forth for claims 76-79, 90-93 and 95-111 in the Official action mailed December 11, 2001. In the Official action mailed December 11, 2001 the rejection is repeated for the reasons of record as set forth in the Official action mailed 6/25/01.

Claims 78, 96, 108, and 117-120 have been cancelled without prejudice.

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The Official action mailed 6/25/01 states the following:

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the invention of Rao to substitute an endosperm-specific promoter, as admitted by Applicant to have been known in the art, for the constitutive promoter, because the invention was clearly directed to modification of seed tissue, and especially endosperm. The different promoters are functional equivalents, and it would have been obvious to substitute one functional equivalent for another. Hordothionine is a seed protein and hence expression in the seed (the major portion of which is endosperm) would be expected to be successful. Also, it was well known in the art that increased nutritional value of seeds was particularly desirable given the importance of grains as a food source in the impoverished regions of the world. One would have had a reasonable expectation of success in view of the success of Rao.

The Examiner is requested to support the above conclusory statements: for example that promoters are functional equivalents.

Rao discloses a high methionine engineered hordothionin protein.

In column 5, lines 7-9 the '802 patent reads that "the plant expression cassette preferably includes a strong **constitutive** promoter sequence at one end to cause the gene to be transcribed at a high frequency", thus teaching away from using an endosperm-preferred promoter. The current claims require an endosperm-preferred promoter.

Therefore, there is no motivation to use an endosperm-preferred promoter to modify the invention of Rao '802. "Even when obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference", *In re Kotzab*, 208 F.3d 1352, 54 USPQ2d 1308 (Fed. Cir. 2000).

The Examiner has provided no motivation to make the necessary modifications and thus has not made a *prima facie* obvious case over Rao '802.

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Claims 78, 79, 90, 96, 103, 105, 108, and 112-120 remain rejected under 35 USC 103(a) as being obvious over Rao et al (US Patent 5,990,389) in view of applicant's admission. In the Official action mailed December 11, 2001 the rejection is repeated for the reasons of record as set forth in the Official action mailed 6/25/01.

The Office Action states: "The Examiner maintains that it would have been obvious to substitute an endosperm preferred promoter in the method of Rao given that Rao's invention is drawn to producing elevated levels of methionine in seeds."

Claims 78, 96, 108, and 117-120 have been cancelled without prejudice.

It is noted that US Patent 5,990,389 is not drawn to elevated levels of methionine in seeds, but elevated levels of lysine. It is assumed for the sake of expediting prosecution the Office action intended to state lysine.

The Official action mailed 6/25/01 states the following:

It would have been prima facie obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the invention of Rao to substitute an endosperm-specific promoter, as admitted by Applicant to have been known in the art, for the constitutive promoter, because the invention was clearly directed to modification of seed tissue, and especially endosperm. The different promoters are functional equivalents, and it would have been obvious to substitute one functional equivalent for another. Hordothionin is a seed protein and hence expression in the seed (the major portion of which is endosperm) would be expected to be successful. Also, it was well known in the art that increased nutritional value of seeds was particularly desirable given the importance of grains as a food source in the impoverished regions of the world. One would have had a reasonable expectation of success in view of the success of Rao.

The Examiner is requested to support the above conclusory statements, for example that promoters are functional equivalents.

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Rao discloses a high lysine engineered hordothionin protein. The '389 patent also discloses that "the plant expression cassette preferably includes a strong **constitutive** promoter sequence at one end to cause the gene to be transcribed at a high frequency". See column 4, lines 65-67 of the '389 patent. Thus the '389 patent also teaches away from using an endosperm-preferred promoter. The current claims require endosperm-preferred promoter.

The Examiner has provided no motivation to make the necessary modifications and thus has not made a *prima facie* obvious case over Rao '389.

"When determining the patentability of a claimed invention which combines two known elements, the question is whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination." *In re Beattie*, 974 F.2d 1309, 1311-12, 24 U.S.P.Q.2D 1040, 1042 (Fed. Cir. 1992) (quoting *Lindemann*, 730 F.2d at 1462, 221 U.S.P.Q. at 488).

In the present case, the prior art as a whole would lead one away from using the present claimed combination. Nothing in the prior art as a whole would suggest the desirability or the likelihood of success when combining the elements of the present claimed invention, i.e. a seed endosperm-preferred promoter operably linked to an HT12 polynucleotide.

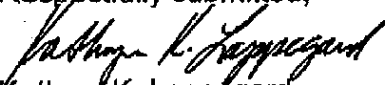
In the Official Office action mailed 11/18/03 the Examiner questions the value of the results in the specification and the Declaration. It is submitted that absent a *prima facie* showing of obviousness, no unexpected results are necessary.

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Conclusion

In view of the above comments and amendments, withdrawal of the outstanding rejections and allowance of the remaining claims is respectfully requested.

Respectfully submitted,


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